Complete Summary

GUIDELINE TITLE

ACE inhibitor and angiotensin II antagonist combination treatment.

BIBLIOGRAPHIC SOURCE(S)

Nicholls K. ACE inhibitor and angiotensin II antagonist combination treatment. Nephrology 2006 Apr;11(S1):S98-9.

Nicholls K. ACE inhibitor and angiotensin II antagonist combination treatment. Westmead NSW (Australia): CARI - Caring for Australasians with Renal Impairment; 2005 Sep. 5 p. [5 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Diabetic nephropathy

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Nephrology
Pharmacology

INTENDED USERS

Pharmacists
Physicians

GUIDELINE OBJECTIVE(S)

To review the data on dual renin angiotensin system (RAS) therapy

TARGET POPULATION

Patients with diabetic nephropathy:

- Patients with type 1 and type 2 diabetes

INTERVENTIONS AND PRACTICES CONSIDERED

Antihypertensive therapy

- Dual blockade with angiotensin converting enzyme inhibitor and angiotensin II antagonist

MAJOR OUTCOMES CONSIDERED

- Goal blood pressure
- Renal function
    - Albuminuria
    - Glomerular filtration rate
    - Side effects of dual blockade therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Databases searched: The Cochrane Renal Group Specialised Register was searched for randomised controlled trials relating to the prevention of progression of kidney disease in people with diabetes mellitus type 1 and type 2. Specific interventions included antihypertensive therapies, angiotensin-converting enzyme (ACE) inhibitors, angiotensin-II receptor antagonists, calcium channel blockers,

dietary protein restriction and glucose control, and interventions to control hypercholesterolemia and hyperlipidemia.

Date of search: 16 December 2003.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Recommendations of Others. Recommendations regarding angiotensin-converting enzyme (ACE) inhibitor and angiotensin II antagonist combination treatment in patients with diabetic nephropathy from the following groups were discussed: Kidney Disease Outcomes Quality Initiative, United Kingdom Renal Association, Canadian Society of Nephrology, European Best Practice Guidelines, and International Guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the levels of evidence (I–IV) can be found at the end of the "Major Recommendations" field.

Guidelines

No recommendations possible based on Level I or II evidence.

Suggestions for Clinical Care

(Suggestions are based on Level III and IV sources)

- There is currently insufficient evidence that angiotensin-converting enzyme inhibitors (ACEI) and angiotensin II receptor antagonists are of additive specific benefit in diabetic nephropathy, beyond additional antihypertensive benefit.
- Although dual blockade is not yet established as a first-line treatment for all patients with diabetic nephropathy, it may be helpful in reaching treatment goals for blood pressure (BP) and albuminuria in individual patients.
- Both ACEIs and angiotensin receptor blockers (ARBs) should be suspended in situations where studies demonstrate that dual blockade water and sodium depletion is present, e.g., in gastroenteritis.
- Studies demonstrate that dual blockade causes hypotension in 5% of patients, hyperkalaemia in 3%, and an increase in creatinine in 8%.

Definitions:

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of hypertension in patients with diabetic nephropathy

POTENTIAL HARMS

Dual blockade causes hypotension in 5% of patients, hyperkalemia in 3%, and an increase in creatinine in 8%.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Apr

GUIDELINE DEVELOPER(S)

Caring for Australasians with Renal Impairment - Disease Specific Society

SOURCE(S) OF FUNDING

Industry-sponsored funding administered through Kidney Health Australia

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

David Harris, Convenor (Westmead, New South Wales); Merlin Thomas (Prahran, Victoria); David Johnson (Woolloongabba, Queensland); Kathy Nicholls (Parkville, Victoria); Adrian Gillin (Camperdown, New South Wales)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All guideline writers are required to fill out a declaration of conflict of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Caring for Australasians with Renal Impairment (CARI) Web site.

Print copies: Available from Caring for Australasians with Renal Impairment, Locked Bag 4001, Centre for Kidney Research, Westmead NSW, Australia 2145

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- The CARI guidelines. A guide for writers. Caring for Australasians with Renal Impairment. 2008 Jul. 6 p.

Electronic copies: Available from the Caring for Australasians with Renal Impairment (CARI) Web site.

PATIENT RESOURCES

None available

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